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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,262	04/08/2004	Terri H. Finkel	CHOP.0190US	8961
110 7590 01/18/2007 DANN, DORFMAN, HERRELL & SKILLMAN 1601 MARKET STREET SUITE 2400 PHILADELPHIA, PA 19103-2307			EXAMINER VENCJ, DAVID J	
			ART UNIT 1641	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/18/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/820,262

Applicant(s)

FINKEL ET AL.

Examiner

David J. Venci

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on October 24, 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☒ Claim(s) 6 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/24/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

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DETAILED ACTION

Claim Objections

System claim 6 is objected to for referencing method claim 4. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1:

In step a), the term "contacting" is indefinite. The identity of one or more objects referenced by "contacting" is not clear. Whether step a) requires contacting a "solid surface" AND/OR "a solid surface with a lipid layer" is not clear. The identity of two or more objects subject to contacting "a solid surface with a lipid layer" is not clear.

In step b) and step c), the term "functionally" is indefinite. The identity of necessary and sufficient structural requirements for a "functional" link is not clear. The identity of necessary and sufficient objects and/or steps required for performing "functional" linking is not clear.

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In step b), the phrases "said first binding pair member", "said second member" and "said first member" lack antecedent bases.

In step c), the phrases "said second binding pair member" and "said lipid" lack antecedent basis.

In claim 2, the term "functionally" is indefinite. The identity of necessary and sufficient structural requirements for a "functional" link is not clear. The identity of necessary and sufficient objects and/or steps required for performing "functional" linking is not clear.

In claims 3, 4, 11 and 12, the mere declaration of a "cell" or "virus" in the "method for producing" of claim 1, absent a description of their structural cooperative relationships with the elements of claim 1, appears incomplete for omitting essential steps or essential structural cooperative relationships. See MPEP § 2172.01.

In claim 6, the identity of one or more objects referenced by most of the recited abbreviations lacks antecedent basis in claim 6 and antecedent support in the specification.

Claim 7 does not comply with the requirements of 35 USC 112, second paragraph, because claim 7 recites the trademark/trade name BIACORE. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is unclear because the trademark or trade name does not describe the particular product, but rather identifies its commercial source.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 7, 8, 10 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Samuelson *et al.* (US 5,260,004).

Samuelson *et al.* describe a method for producing a fluid planar lipid layer-based membrane-anchored ligand system comprising:

- a. contacting (see *e.g.*, Abstract, second sentence, "spreading") a solid surface (see *e.g.*, col. 6, line 27, "Lauda MGW Filmwaag troughs") with a lipid bilayer containing lipids conjugated to a first specific binding pair member (see Abstract, second sentence, "biotinylated lipids");
- b. functionally linking (see *e.g.*, Abstract, third sentence, "[c]onjugated") a ligand (see Abstract, third sentence, "proteinaceous component") to a second specific binding pair member which has binding affinity for said first binding pair member (see Abstract, third sentence, "a biotin-binding component made up of an avidin or streptavidin"); and
- c. contacting the lipid layer of step a) with the linked ligand of step b) (see col. 4, lines 30-32, "the conjugated molecules also may be added to the subphase during or after compression of the interface") whereby contact of the lipid layer with said second binding pair member functionally linked to said ligand results in anchoring of the ligand to said lipid (see Abstract,

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fourth sentence, "[b]ecause of the affinity between biotin and the biotin-binding component, the conjugated molecules bind to the biotinylated lipids"), thereby forming a fluid planar lipid layer-based membrane-anchored ligand system.

Claims 1, 2, 5, 7, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Penner *et al.* (US 4,830,952).

Penner *et al.* describe a method for producing a fluid planar lipid layer-based membrane-anchored ligand system comprising:

- a. contacting a solid surface (see col. 14, line 29, "moving the support through a liquid interface") with a lipid layer containing lipids (see col. 4, lines ~37-38, noting the layer closest to the "substrate") conjugated to a first specific binding pair member (see *e.g.*, col. 6, "L₂" group; line 30, "choline");
- b. functionally linking a ligand (see col. 5, lines 47-48, "Z represents one or more charge balancing counter ions"; lines 66-68, "Z can be a substituent of R¹, R², or R³") to a second specific binding pair member (see col. 5, Formulae III, IV, and V) which has binding affinity (see col. 4, line 26, "more stable") for said first binding pair member (see col. 4, lines ~32-36, noting the proximity of "L" groups between the top layer and the middle layer); and
- c. contacting (see col. 14, line 29, "moving the support through a liquid interface") the lipid layer of step a) with the linked ligand of step b) whereby contact of the lipid layer with said second binding pair member functionally linked to said ligand results in anchoring of

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the ligand to said lipid (see col. 4, lines ~32-36, noting the proximity of "L" groups between the top layer and the middle layer), thereby forming a fluid planar lipid layer-based membrane-anchored ligand system.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 4, 6, 11 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samuelson *et al.* (US 5,260,004) in view of Ladner *et al.* (US 5,223,409).

Samuelson *et al.* describe a method for producing a lipid-ligand system as substantially described *supra*.

Samuelson *et al.* do not describe a method incorporating a "cell" or "virus".

However, Ladner *et al.* describe optimization of affinity separation technology (see col. 83, lines 25+) incorporating a "cell" or "virus" (see Abstract).

It would have been obvious to a person of ordinary skill to optimize the lipid-ligand system of Samuelson *et al.* by incorporating a "cell" or "virus" because Ladner *et al.* discovered that such optimization provides "a novel binding domain having a desired affinity" (see Abstract, fifth sentence).

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samuelson *et al.* (US 5,260,004) in view of Sivars *et al.*, 743 J. CHROMATOGR. B 307 (2000).

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Samuelson *et al.* describe a method for producing a lipid-ligand system as substantially described *supra*.

Samuelson *et al.* do not describe a method incorporating "nickel-histidine" binding pairs.

However, Sivars *et al.* describe optimization of affinity separation (see Title, "Affinity partitioning") incorporating poly(histidine)-metal binding pairs (see Title; see *also*, p. 312, left column, first full paragraph, "the general binding strength of chelated metal ions towards histidines decreases in the order: $\text{Cu}^{2+} > \text{Ni}^{2+} > \text{Zn}^{2+} > \text{Co}^{2+}$ ").

It would have been obvious to a person of ordinary skill to optimize the lipid-ligand system of Samuelson *et al.* by incorporating poly(histidine)-metal binding pairs because Sivars *et al.* discovered that such optimization provides "a fast and mild affinity procedure for the purification of integral membrane proteins" (see Abstract, last sentence).

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Conclusion


No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David J Venci
Examiner
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